

27049. Vitamin tablets. (F.D.C. No. 42435. S. No. 30-961 P.)

INFORMATION FILED: 4-30-59, Dist. Mass., against Cowley Pharmaceuticals, Inc., and Benjamin (Ben) C. Cowley, president, Auburn, Mass.

SHIPPED: 10-29-57, from Massachusetts to New York.

LABEL IN PART: "Tablets METAVITES."

CHARGE: 403(a)—the label statements, "Each tablet contains: Vitamin A 10,000 units, Vitamin D 1,000 units, Vitamin B-1 (Thiamin HCl) 6 mg., * * * Vitamin C (Ascorbic Acid) 50 mg., Niacinamide 10 mg. * * * Vitamin B-12 * * * 3 mcg." were false and misleading since each tablet of the article contained less than those amounts of vitamin A, vitamin D, vitamin B-1, vitamin C, niacinamide, and vitamin B-12.

The information also alleged that 4 other products, namely, Cowlserpa (reserpine) tablets, atropine sulfate tablets, digitalis tablets, and Salamin tablets, were misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 6215.

PLEA: Guilty.

DISPOSITION: 5-23-60. Corporation—\$500 fine. Cowley—\$1,000 fine, \$500 of which was suspended, and probation for 1 year.

27050. Yeast culture wafers. (F.D.C. No. 44605. S. No. 43-668 R.)

QUANTITY: 230 cases, each containing 72 60-wafer btl. at Seattle, Wash., in possession of Genius, Inc.

SHIPPED: Between 3-1-60 and 4-5-60, from Chillicothe, Ill., by Newhaven Laboratories.

LABEL IN PART: (Btl.) "Western Yeast Culture A Food Supplement with Vitamin B Complex and Vitamins A and D * * * Each Wafer contains * * * with Vitamin B Complex and Vitamin A and D additions to Vitamins as listed below Vitamin B₁ (Thiamin Mononitrate) 2 mg. Vitamin B-2 (Riboflavin) 2.4 mg. Vitamin B-6 (Pyridoxine Hydrochloride) 1 mg. Vitamin B-12 Cobalamin Concentrate NF) 1 microg. Calcium Pantothenate 2 mg. Acid Nicotinic 10 mg. Folic Acid 0.25 mg. Vitamin A (Acetate) 4000 Units Vitamin D (Irradiated Yeast) 600 Units Powdered Sugar Excipient added * * * The need for Folic Acid, Pyridoxine Hydrochloride, Calcium Pantothenate and Vitamin B-12 has been established * * * Distributed by Western Products South 5th and Broadway, Tacoma 2, Washington."

ACCOMPANYING LABELING: Leaflets entitled "The Western Yeast Story," "S-1 Direct Retail Buyer," "S-2 Wholesale Buyer" and "S-3 Retailer"; placards entitled "As Advertised by Bob Hale"; and cards reading in part "I'll Send You \$2.50 for this card."

RESULTS OF INVESTIGATION: The circulars and placards were designed and printed by Genius, Inc., and were used in promoting sales of the article.

LIBELED: 6-10-60, W. Dist. Wash.

CHARGE: 403(a)—when shipped and while held for sale, the label statement "Western Yeast Culture A Food Supplement" was false and misleading since it suggested and implied that the vitamin content of the article was primarily due to the yeast, whereas the yeast was only a vehicle for the added vitamins which were the primary source of the vitamin content; the labeling statement that the product had been found to aid in more rapid and thorough assimilation, represented that the article was better than other similar food supple-